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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/509,283	08/11/00	KROCZEK R	50125/011001

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EXAMINER	
ROARK, J	
ART UNIT	**PAPER NUMBER**
1644	7

DATE MAILED: 11/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/509,283	KROCZEK, RICHARD	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 53-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-28 and 53-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Notice to comply with Sequnce Rules* .

DETAILED ACTION

1.Applicant's amendment, filed on 8/15/00 (Paper No. 6), is acknowledged.
Claims 1, 2, and 11-14 have been amended.
Claims 29-52 have been cancelled.
Claims 53-70 have been added.

Claims 1-28 and 53-70 *are pending and being acted upon presently*

Sequence Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is reminded to amend the specification (including the Brief Description of Drawings) and claims as appropriate to reflect compliance with the Sequence Rules.

Election/Restrictions

3. The following is noted:
Claims 23, 53, 56, 61 and dependent claims recite a "substance" which the specification and claims indicate can be an antibody, ligand, agonist, or antagonist (non-antibody). Antibodies, ligands, agonists, and antagonists (non-antibody) differ with respect to their structure, physiochemical properties, and mode of action. A person of ordinary skill in the art would not envision one in view of the other.

Claims 68 and 69 also recite a "substance", but do not appear to provide an indication of what the "substance" is. If the "substance" is also intended to encompass compounds with diverse structures and physiochemical properties, then claims 68 and 69 will be subject to additional restriction requirements.

Claims 57-60 recite pharmaceutical compositions comprising either a costimulating molecule or a cell expressing said molecule. These pharmaceutical compositions differ with respect to their structure, physiochemical properties, and modes of action. A person of ordinary skill in the art would not envision one in view of the other.

Therefore, the restriction has been set forth for each as a separate group, irrespective of the format of the claims.

4. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-3, 57-58, drawn to a costimulating *molecule* and pharmaceutical compositions thereof.

II. Claims 4-14, drawn to a DNA encoding a costimulating molecule, vectors, hosts cells, and a method of preparing.

III. Claims 15-22 and 53-55 and 70, drawn to antibodies to a costimulating molecule, pharmaceutical compositions thereof, hybridomas producing said antibodies, and a method of producing antibodies to said molecule.

IV. Claims 23-28, and 56 drawn to the use of substance which inhibits a costimulating molecule in a method of treating or preventing, wherein the substance is an *antibody*.
V. Claims 23-28, and 56 drawn to the use of substance which inhibits a costimulating molecule in a method of treating or preventing, wherein the substance is a *ligand*.
VI. Claims 23-28, and 56 drawn to the use of substance which inhibits a costimulating molecule in a method of treating or preventing, wherein the substance is an *agonist*.
VII. Claims 23-28, and 56 drawn to the use of substance which inhibits a costimulating molecule in a method of treating or preventing, wherein the substance is a non-antibody *antagonist*.

VIII. Claims 53-55, drawn to a pharmaceutical composition comprising an inhibitor, wherein the inhibitor is a *ligand*.
IX. Claims 53-55, drawn to a pharmaceutical composition comprising an inhibitor, wherein the inhibitor is an *agonist*.
X. Claims 53-55, drawn to a pharmaceutical composition comprising an inhibitor, wherein the inhibitor is a non-antibody *antagonist*.

XI. Claims 57-58, drawn to a pharmaceutical composition comprising a cell expressing a costimulating molecule.

XII. Claims 59-60, drawn to a method of treating comprising administering a costimulatory *molecule*.
XIII. Claims 59-60, drawn to a method of treating comprising administering a *cell expressing a costimulatory molecule*.

XIV. Claims 61-65, drawn to a method of diagnosing by contacting a sample with a substance, wherein the substance is a *nucleic acid*.
XV. Claims 61 and 66-67, drawn to a method of diagnosing by contacting a sample with a substance, wherein the substance is an *antibody*.
XVI. Claims 61 and 66, drawn to a method of diagnosing by contacting a sample with a substance, wherein the substance is a *ligand*.
XVII. Claims 61 and 66, drawn to a method of diagnosing by contacting a sample with a substance, wherein the substance is an *agonist*.
XVIII. Claims 61 and 66, drawn to a method of diagnosing by contacting a sample with a substance, wherein the substance is a non-antibody *antagonist*.

XIX. Claim 68, drawn to a pharmaceutical composition comprising a substance which modulates a signal transduction pathway of a costimulating molecule.

XX. Claim 69, drawn to a pharmaceutical composition comprising a substance which prevents up-regulation of the costimulating molecule.

6. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of WO98/38216 (Sept 3, 1998, IDS) (see entire document).

As noted on the International Search Report, GENESEQ accession number V53199 correspond the SEQ ID NO:2 consisting of the amino acid sequence of the costimulatory molecule 8F4.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

7. This application contains claims directed to the following patentably distinct species of the claimed Inventions IV/V/VI/VII: wherein the method is:

A) treatment of autoimmune disease,
B) prevention of rejection reactions of organ transplants, or
C) treatment of dysregulation of the immune system.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus the conditions each represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27, 28, and 56 are generic.

8. This application contains claims directed to the following patentably distinct species of the claimed Invention XII/XIII: wherein the method of treatment is for:

A) cancer,
B) AIDS,
C) an asthmatic disorder, or
D) chronic viral disease.

In addition, if species D is elected, a subspecies election is required between:

i) HCV, or
ii) HBV.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus the conditions each represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 59 is generic.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
November 20, 2000

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PRIMARY EXAMINER
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11/22/00